K000693

Appendix E : Summary of Safety and Effectiveness Data

General Information and Description

The Umeco Optima Multiline system is based on an optical cavity containing a Nd:YAG laser rod, which is activated by means of the use of flashlamps. After the cavity,a red helium neon aiming beam is reflected onto a coaxial beam path using a beamsplitter assembly. The combined therapuetic and aiming beams are guided down an articulated arm delivery system to a focusing handpiece. The laser is used in non-contact mode.

The System is capable of emitting up to 1.0 Joules of light at 1064 nm and up to 0.6 Joules of light at 532nm, with a nomimal pulsewidth of 10 nanoseconds. The laser is intended to be used for intended for the removal of tattoos and benign pigmented lesions in dermatology and plastic surgery.

The Nd:YAG laser system is designed with 3 major sub-systems:

a) An articulated arm delivery system terminated in a focusing handpiece.

b) An electronic power supply and interface circuitry.

c) An optical chamber containing laser rod and laser cavity optics.

No accessories are available for use with the Optima Multiline laser system.

Summary of Substantial Equivalence

Umeco believes that its Optima Multiline laser is substantially equivalent to the Derma-Lase DLR-1 (K913256) and Continuum Biomedical Medlite (K#915497 and later clearance numbers) laser systems.

The Derma-Lase DLR-1 Ruby laser system is intended for the removal of tattoos and benign pigmented lesions. The Continuum Biomedical Medlite Nd:YAG laser system is intended for the removal of tattoos and benign pigmented lesions. These systems therefore have the same Intended Use as the Optima Multiline laser system.

All three lasers emit at wavelengths in the range of 532nm - 1064nm, a range which is highly absorbed in the ink comprising tattoos and in the naturally occurring melanin comprising benign pigmented lesions. All three lasers are therefore absorbed in a small volume of tissue pigment, allowing for very precise action on the target tissue components.

All three lasers have a nominal pulsewidth in the range 10-30 nanoseconds and therefore realize similar peak power with minimal thermal conduction during the pulse.

All three lasers offer a range of available spotsizes with diameter in the range 2 - 8 mm.

All three lasers utilize an articulated arm delivery system for maximum flexibility and reliability, together with class I aiming beams which pose no hazard to the user.

All three systems utilize an internal closed loop water-air hear exchanger circuit for optimal thermal control of the laser cavity.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 6 2000

Iain D. Miller, Ph.D.
President
Medical Laser Solutions, LLC
36 Mystic Street
Charlestown, Massachusetts 02129

Re: K000693
Trade Name: Umeco Optima Multiline
Regulatory Class: II
Product Code: GEX
Dated: February 25, 2000
Received: March 1, 2000

Dear Dr. Miller:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix F

510(k) Number (if known): K000693

Device Name: Umeco Optima Multiline

Indications for Use:

The Umeco Optima Multiline system is intended for the use in the removal of tattoos and benign pigmented lesions in dermatology and plastic surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anne R. Lochner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000693

Prescription Use ✓ OR Over-the-counter use _____
(Per 21 CFR 801.109)